genzyme
tissue repair

GENZYME CORPORATION
64 SIDNEY STREET
CAMBRIDGE, MA 02139-4136
TEL 617-494-8484
FAX 617-494-6561

July 6, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **Docket No. 99D-0557**
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans

Genzyme Tissue Repair wishes to submit the following comments for consideration in response to the draft guideline "Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans" published in the Federal Register on April 6, 1999 (Docket 99D-0557). The guideline seeks to provide guidance to industry on three points:

1. The potential health risks posed by nonhuman primate xenografts
2. The need for further scientific research and evaluation of these risks, particularly infectious agents
3. The need for public discussion concerning these issues.

We agree with the Food and Drug Administration's position that the use of nonhuman primate cells, tissues and organs deserves special consideration. We also agree that the definition in the draft document for use of non-human primate xenografts in humans is appropriate for those materials.

At this time, we would like to state that the definition of xenotransplantation presented in the draft guideline published September 23, 1996 ("Draft Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation"), appropriately encompasses all other products that should be considered xenografts.

Any decision to modify the definition of xenotransplantation presented in the September 23, 1996 guideline will affect a number of other products not currently classified as xenografts. Broadly applying a definition of xenotransplantation would significantly change the regulatory environment for these products, potentially applying unnecessary requirements.

We recognize the effort the Agency has put forth to engage industry on this topic (June 3-4 Biologic Modifiers Advisory Committee). Continued dialogue between the Agency and industry is critical prior to any further expansion of the definition of xenotransplantation or the application of such definition. In this way, the Agency and industry can craft regulation and guidance that protects the public health meets the Agency's stated objective of public discussion regarding the issues associated with xenotransplantation while maintaining a regulatory environment that fosters the development of important and potentially life saving therapies.

Sincerely,

Gregory Dombal
Manager, Regulatory Affairs
Genzyme Tissue Repair

C185

99D-0557

SHIPPER'S FEDEX ACCOUNT NUMBER

FedEx.

FROM:
MARIA CIFUENTES
GENZYME TISSUE REPAIR
64 SIDNEY STREET

PHONE: (617)761-8215

SHIP DATE: 13JUL99
MAN WGT: 1 LBS

CAMBRIDGE MA 021394136

TO: PHONE: (617)494-8484

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, RM 1061

ROCKVILLE MD 20852

REF: 360-45877

DELIVERY ADDRESS
TRK # 7907 6255 7030
FORM ID: 0201
20852-MD-US

PRIORITY OVERNIGHT

IAD

ZM EDG

WED
AA

Deliver by:
14JUL99

Fold Here

Next Step

To print a receipt of your shipment, please click on "Shipping History".

Ship Another Package | Schedule Courier | Find a Dropoff Location | Shipping History

Shipment Complete | Cancel Shipment

To prepare your package for shipment, you must do the following: Use the PRINT feature from your browser to print this page to your laser printer. Fold the printed page in half